Human Subjects Electronic Research Application

Overview for IRB Members

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Human Subjects Electronic Research Application

- HS-ERA (Human Subjects Electronic Research Application) is Penn's online IRB submission system.

- The system was developed in 2008 and became mandatory in 2011.

- The first half of the application contains institutional information such as study personnel, sponsor information, questions for institutional ancillary reviews, institutional policy questions, and information about external sites for sIRB protocols.

- The latter portion of the application contains information that would typically be included in an IRB Protocol.

- To streamline the review process, researchers are encouraged to include references to a full standalone protocol, if available, in cases where they would otherwise be copy/pasting the information. A grant application may not serve as an IRB Protocol.

- Research of lesser complexity may utilize HSERA as the IRB protocol.

HS-ERA Instructions

HS-ERA is available to all researchers at Penn with a valid PennKey and Password.

1. Go to https://medley.isc-seo.upenn.edu/hsProtocol/jsp/fast.do

2. Authenticate with your PennKey and PennKey password.

3. The Human Subjects Electronic Research Application (HS-ERA) home page will appear.

To locate a protocol, click on "Review Submissions" under "Board Members" on the left side of the screen...

Type in the Protocol number then click the "Filter" button.

Do not press enter on your keyboard. This will bring you to a different screen. If this happens click the back button.

TO SORT: Click the blue column headings (submission date, type, etc.).

TO VIEW A SUBMISSION: Click "Review" on the far-right side.

Find Submissions

Find submissions created using this system

Confirmation #	
Principal Investigator	None **Set**
Assigned To	None **Set**
Submitted after	
Submitted before	
Board number	-- select --
Protocol #	811685
PennERA Protocol Status	--select--
Meeting date after	
Meeting date before	

Filter **Clear filter**

Click on any column heading to sort by that column
Pages: 1 **2 3 4 Next**

Type	Principal Investigator	Submission Date	IRB Received Date	Title	Status	Penn ERA Protocol Board	Confirmation Number	Protocol Number	PennERA Protocol Status	Meeting Date		
Modification	MANDELL, DAVID S	12/18/2014	12/18/2014	Clinical Algorithm	Assigned to IRB #8	IRB #8	bhbaejdc	811685	Approved		👓	**Review**
Modification	MANDELL, DAVID S	12/05/2014	12/05/2014	Clinical Algorithm	Assigned to IRB #8	IRB #8	bhabbeda	811685	Approved		👓	**Review**
Continuing Review	MANDELL, DAVID S	11/03/2014	11/03/2014	Clinical Algorithm	Assigned to IRB #8	IRB #8	bggbgjcj	811685	Approved	11/24/2014	👓	**Review**

Find a Protocol Submission

To see a Review History of a particular submission: click the **eyeglasses button** next to "Review". The eyeglass's view is strictly an overview of the actions by the IRB staff as it relates to the submission (comments regarding the review, the review decision, and decision letter). On this page there will be a listing of hyperlinks in the middle of the page.

The Review History view **will also allow you to view the application as a PDF. After clicking the eyeglasses,** click the blue View as PDF button on the top right if you wish to download a PDF of the application.

Back to submission list | View as Pdf | Printer friendly

Find Submissions

Find submissions created using this system

Confirmation #	
Principal Investigator	None **Set**
Assigned To	None **Set**
Submitted after	
Submitted before	
Board number	-- select --
Protocol #	811685
PennERA Protocol Status	--select--
Meeting date after	
Meeting date before	

Filter   **Clear filter**

Click on any column heading to sort by that column

Pages: 1 **2 3 4 Next**

Type	Principal Investigator	Submission Date	IRB Received Date	Title	Status	Penn ERA Protocol Board	Confirmation Number	Protocol Number	PennERA Protocol Status	Meeting Date		
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Review History (Eyeglasses) 👓

On this page there will be a listing of submissions in the middle of the page.

This example below shows a list of links indicating that the submission was returned to the study team 4 times by the IRB staff. You can see that each time a submission is returned to the IRB, it is given a new confirmation code (in parentheses).

Clicking these hyperlinks will take you to the eyeglasses view of each edition of the submission. To review any of these submissions in their entirety (i.e., the application content and changes made by the study team), the confirmation code that corresponds to the submission should be entered on the "Find Submissions Page" in the same way you would search for a protocol.

If a submission was received without returning it to the study team, this submission will not be hyperlinked (first line, submission beccadef below).

Assigned to IRB #5, created on 11/27/2013 (beccadef) [IRB Administrator = LESAGE, STEPHANIE G]
Returned by ORA, created on 11/21/2013 (bebgfgcd) [IRB Administrator = DAVISON, CHRISTINE M]
Returned by ORA, created on 09/27/2013 (bdggheec) [IRB Administrator = DAVISON, CHRISTINE M]
Returned by ORA, created on 09/12/2013 (bdfcebdf) [IRB Administrator = DAVISON, CHRISTINE M]
Returned by ORA, created on 07/23/2013 (bdafhhig) [IRB Administrator = DAVISON, CHRISTINE M]

Review History (Eyeglasses) (continued)

Review History (Eyeglasses) 👓 (continued)

- There are instances where the decision made by the IRB results in a new submission being required to make the requested edits. In these cases, the submission that contains the response will not be hyperlinked in this fashion.

- Common examples of this are:

    - Responses to conditional reapproval of continuing reviews. These will typically be modifications.

    - Responses to deviations or reportable event submissions where the board requested more information or changes to a CAPA.

Reviewing the Application

- This is an example of an Initial Protocol Application submission that was returned for edits before approval.

- Clicking "show clean" will expand each individual section for review of content. The linked text of "show clean" will change to "hide clean" to collapse that section when you are finished viewing it.

- Selecting "show tracked" will display tracked changes to that section if any changes were made.

- To view the entire application in a seamless screen to scroll through, select the "Clean protocol application" at the top of the page.

Protocol Application Form

You may view the entire protocol application form:

Clean protocol application (shows printer-friendly version)

Protocol application w/ tracked changes (shows printer-friendly tracked v

OR

You may view the protocol application form by section:

IRB Facesheet

Basic Info	show clean	show tracked
Personnel	show clean	
Bio	show clean	show tracked
Sponsors	show clean	
Sites	show clean	

Protocol Summary

Protocol	show clean	show tracked
Populations	show clean	show tracked
Procedures	show clean	show tracked
Consent	show clean	show tracked
Risk/Benefit	show clean	show tracked

Reviewing the Application

- Clicking "show attached documents" will expand a list of the documents previously uploaded before the submission was returned.

- Clicking "show comments" will display the comments from IRB staff and reviewers as they appear in the eyeglasses view previously mentioned.

- Clicking "show IRB correspondence" will display the decision letter and may contain communications from other review entities.

- Clicking "show IRB review history" will display the decision made, the name of the person who made the decision and the date and time the decision was entered.

Documents

show attached documents

Comments

show comments

IRB Correspondence

show IRB correspondence

Ancillary Committee Correspondence

show Ancillary Committee correspondence

IRB Review History

show IRB review history

Submission documents may be downloaded individually by simply clicking on the hyperlink of the document.

To select all documents, click Select all and then Download selected documents in one zip file.

To select some documents, check the box (purple square) of the documents you want to download, then click Download selected documents in one zip file.

Documents

hide documents uploaded with (ebajhihh) created on 05/08/2024

☐ **Continuing Review Form (826244-18316continuingreviewform_05-08-2024.docx**)

☐ **Full sponsor's protocol (2012-0825v.33versiondate02.08.2024clean.pdf)** Date upl

☐ **Additional Document (826244-18316coverletter_05-08-2024.doc)** Date uploaded:

Download selected documents in one zip file | **Select all** | **Deselect all**

show all documents

Downloading Documents

In the comments section, you will see various comments from the IRB staff.

It is important to review this section. Sometimes additional documents received by the team will be uploaded here. Likewise, issues already identified by the staff and communications with the research team will be here.

You may also upload your notes/review worksheets for the IRB staff here.

Documents

show documents uploaded with (cgeihfaa) created on 05/17/2018
show documents uploaded with (cgehagae) created on 05/15/2018
show all documents

Comments

hide comments

Date	From	Comments	Attachment	
06/14/2018	YOOS, JESSICA L *IRB Administrator*	Jessa's questions to the study team; team given DL of 6/21 to respond	responserequired_irbpre-reviewof829978pennyaichatbotshulman.pdf	🗑
06/14/2018	YOOS, JESSICA L *IRB Administrator*	Completeness checklist	2shulman829978initialcompletenesschecklist.docx	🗑
06/14/2018	YOOS, JESSICA L *IRB Administrator*	Jessa's Agenda Notes & Stipulations	1shulman829978convenedagendanotes.doc	🗑
06/14/2018	YOOS, JESSICA L *IRB Administrator*	Device checklist	4shulman829978deviceschecklist_5.2018_final.docx	🗑
06/14/2018	YOOS, JESSICA L *IRB Administrator*	ATTENTION IRB MEMBER: please review this edited version of the consent	shulman829978informedconsentform_penny_jessaedits.docx	🗑

Comments: Finding IRB Staff Screening Materials

Important Tips

- If a protocol or a submission is "Not Found" when searching, double-check that there are no spaces before or after the number.

- Ongoing submissions (modifications, continuing reviews, deviations, exceptions, reportable events) have e-forms in HSERA. **However, these e-forms are no longer used.** Teams are required to upload standalone forms for these submissions.

- Modifications and response submissions have a tracked change function. Not all of these submissions will have tracked changes in HSERA.

- The automatic viewing option allows you to expand and collapse each section of the application. If you would like to see the entire HS-ERA application on one screen, click "Clean Protocol Application" or "Protocol application w/ tracked changes."